REMARKS

By this amendment, Applicants have canceled Claim 9 without prejudice and have added new claim 41 which is clearly supported in the specification and which is the parallel claim to claim 20. Claims 1-8, 10-13, 15-18, 27, and 29-40 were previously withdrawn, and thus Claims 19-26, 28 and 41 are currently pending and under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

In the Official Action dated May 17, 2007 the Examiner rejected claim 9, 19-26, and 28 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserted that claims 9 and 19 are vague and indefinite due to the phrase "antibody that is capable of binding." For the reasons set forth below, Applicants respectfully traverse the Examiner's rejection, insofar as applicable to the pending claims, and request that it be withdrawn.

Applicants respectfully submit that the use of the phrase "antibody that is capable of binding" is not only clearly understandable and definite to one of ordinary skill in the art, the USPTO has stated directly that such language is acceptable under Section 112 for describing an antibody. In particular, in the most recent version of the "Written Description Training Materials," as published by the USPTO on March 25, 2008, the US Patent Office reviewed the claim language "an isolated antibody capable of binding to antigen X" for compliance with the written description requirement, and considered that this language was clearly acceptable for Section

112 written description purposes. See attached excerpts from Written Description Guidelines, Example 13. It is simply inconceivable that the Patent Office would go to the trouble and provide a complete Example whereby language is shown that is considered compatible with Section 112, and yet would be somehow considered "indefinite" under the same statutory provision.

Even further, a quick search of the US Patents database confirms that this language is acceptable in that over 2700 patents have been issued over the years which include the language "an antibody capable of binding [antigen x]", including most recently U.S. Pat. No. 7,288,637. Accordingly, Applicants submit that the language of the present claims is completely acceptable under 35 U.S.C. § 112, second paragraph, and the Examiner's rejection under this provisions is respectfully traversed.

In the Official Action, the Examiner rejected claims 9, 19-26, and 28 under 35 U.S.C. §102(e) and 35 U.S.C. §102(b) as being anticipated by Choi et al. (U.S. 6,448,043) and Choi et al. (WO 9850554), respectively. The Examiner further rejected claims 9, 19-26, and 28 under 35 U.S.C. §102(e) as being anticipated by Doucette-Stamm et al. (U.S. 6,617,156). In making the rejections, the Examiner recognized that these references did not actually produce any antibodies, but indicated that a sequence was disclosed which was allegedly identical to Applicant's SEQ ID NO: 13, and that generating antibodies against this sequence would produce antibodies which wound inherently possess the capability of binding to amino acids 33-592 of SEQ ID NO: 13. For the reasons set forth below, Applicants respectfully traverse the Examiner's rejections and request that they be withdrawn.

As Applicants have previously pointed out, the references cited by the Examiner reflect various computer-generated sequences which were thought via algorithmic methods to reflect actual polypeptides, and do not disclose any specific proteins that may be expressed from such sequences, much less any specific regions therein. In other words, one with possession of the disclosures of the sequences would need to take the steps of actually attempting to prepare polypeptides from such sequences, and would not know aforehand if such theoretical sequences would result in actual polypeptides, much less antigenic polypeptides that would generate any antibodies. Moreover, the reference nowhere states or suggests the presence of particular regions within any theoretical sequences such as the A domain, and thus there is no disclosure in any of the cited references that would teach or remotely suggest a specific region within the purported polypeptides. As such, the cited references do not disclose or point to in any way any particular region within a sequence, much less the specific A domain sequence as reflected in claim 19.

Accordingly, the references do not teach that any particular polypeptide can be expressed, much less be antigenic, and certainly do not teach or suggest any specific region from which to generate a specific antibody. As such, the Examiner's statement the "the antibodies taught by the cited references would inherently possess the capability of binding to amino acids 33-592 of SEQ ID NO: 13" is clearly without support and can only be asserted with the hindsight of Applicants' invention and discovery of the specific A domain of this polypeptide as set forth in SEQ ID NO:13. The Examiner has thus not established a *prima facie* case of anticipation

each and every element of the claimed invention, as arranged in the claim, since the present elements of the claims are not disclosed either specifically or inherently by a single prior art reference. See *Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.* 976 F.2d 1559, 1565 (Fed. Cir. 1992).

In this regard, Applicants respectfully submit that the Examiner has not established that cited references specifically or inherently discloses each and every element of the claimed invention, and instead has only offered conclusory statements that the theoretical antibodies that conceivably could be generated from the sequence of the cited references "inherently possess the capability of binding to amino acids 33-592 of SEQ ID NO: 13." To the contrary, "it is the examiner's burden to provide evidentiary support for his factual finding" that a purported prior art antibody would bind to specific targets. *Ex parte Kung*, 17 U.S.P.Q.2d 1545, 1548 (USPTO Bd. App. and Int. 1989) (the Examiner's mere "invitation to consult a basic immunology text hardly suffices" to support a 102 rejection wherein not all of the claimed elements were present). As reflected above, the cited references only disclose theoretical, computer-generated sequences, much less any specific regions within those sequences, and thus do not anticipate the presently claimed invention relating to isolated antibodies capable of binding to amino acids 33-592 of SEQ ID NO: 13. See also *Ex parte Old, et al.*, 229 USPQ 196, 200 ((PTO Bd. App. And Int. 1985) (uncertainty involved in the generation of antibodies meant that no "expected" results could be said to occur from the knowledge of a specific antigen).

Accordingly, Applicants respectfully submit that the present invention is not anticipated nor made obvious by the cited references, and that the claims of the present application relating to antibodies capable of binding to amino acids 33-592 of SEQ ID NO: 13 are clearly patentable over those references. Applicants thus submit that the Examiner's rejection on the basis of the cited references is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and has been placed in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

Date: May 19, 2008

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REVISION 1
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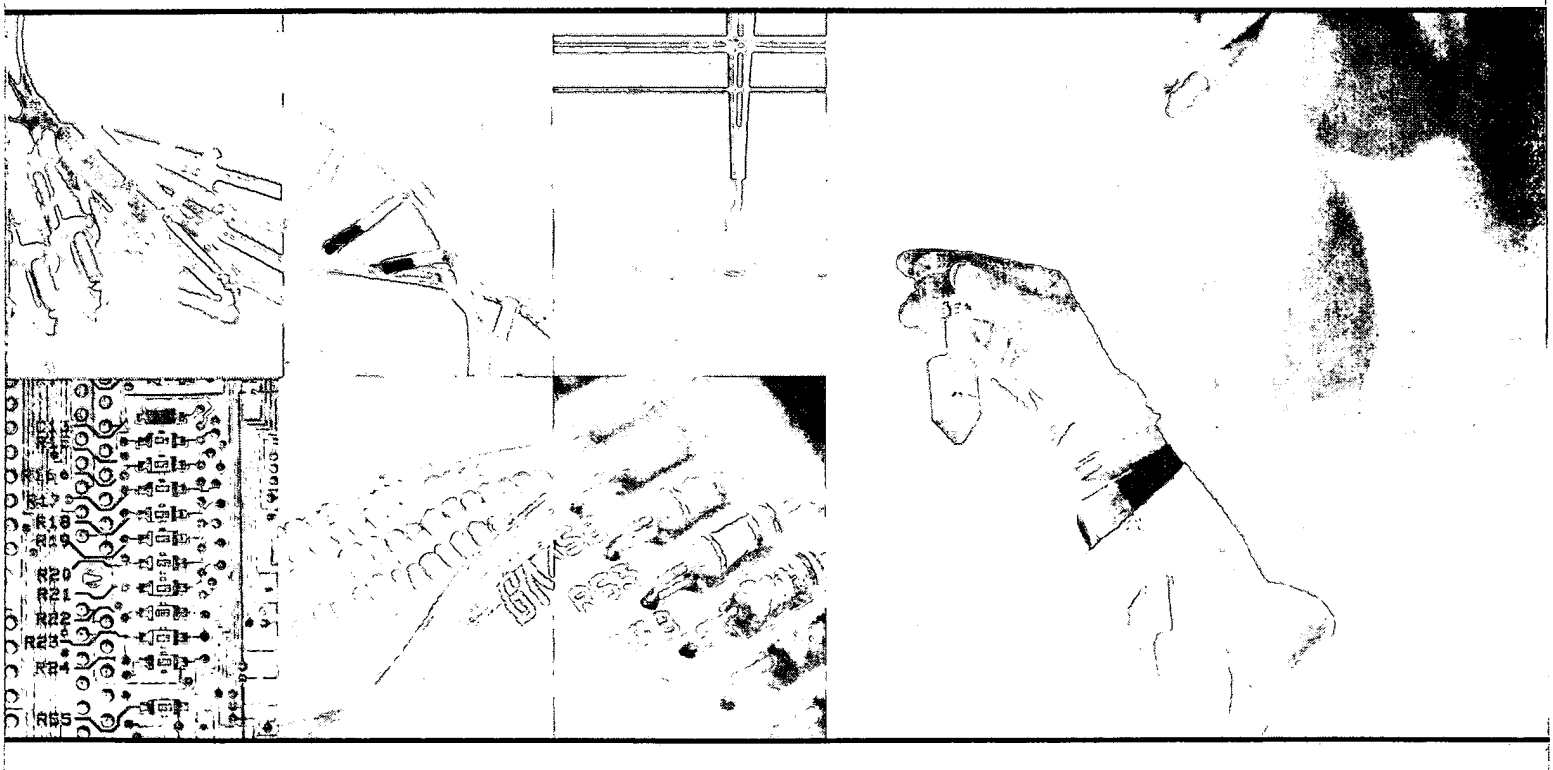
WRITTEN DESCRIPTION TRAINING MATERIALS



EXAMPLE 13: ANTIBODIES TO A SINGLE PROTEIN

Specification:

The specification discloses that a protein designated antigen X has been isolated from HIV and is useful for detection of HIV infections. The specification describes purifying antigen X by gel filtration and discloses its amino acid sequence. Antigen X is further characterized as a 55 kD monomer having no disulfide bonds, with a slightly acidic pI. The specification discusses antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. However, there is no working or detailed prophetic example of an antibody that binds to antigen X.

Claim:

Claim 1. An isolated antibody capable of binding to antigen X.

Analysis:

The specification does not describe an actual reduction to practice of an antibody that binds to antigen X by reference to a deposit (e.g., deposit of a hybridoma) or by describing an antibody in structural terms sufficient to show possession. The specification also does not describe the complete structure of an antibody capable of binding antigen X in detailed drawings or through a structural chemical formula. The specification does not describe a partial structure of the claimed antibody. The specification does not describe any physical or chemical properties of the claimed antibody (e.g., molecular weight, association constant).

TECHNICAL NOTE

As evidence, see, e.g., Elvin A. Kabat, STRUCTURAL CONCEPTS IN IMMUNOLOGY AND IMMUNOCHEMISTRY, 2nd Ed. (Holt, Rinehart and Winston 1976), p. 17:

Early studies empirically established that proteins were good antigens when injected into a species other than the one from which they originated. . . . Indeed, it was shown very early in this [20th] century that rabbit serum proteins injected into even as closely related a species as hare would yield antibody (and vice versa). No difficulties were encountered in preparing antibodies to protein antigens from remotely related sources such as bacteria, viruses, and egg, milk, and plant proteins. In most of these studies it sufficed to immunize the animal (an animal receiving injections of an antigen is being immunized) with a solution of the antigen, or preferably, with the protein antigen adsorbed on flocculles of aluminum hydroxide (alum precipitate), since the use of antigens in particulate form had been shown to give a better antibody response.

Example 13: Antibodies To A Single Protein

The specification does not disclose a correlation between the function of binding to antigen X and the structure of the claimed antibody. Finally, the specification does not describe a method of making an antibody that binds antigen X.

Technical Note

For example, Kabat shows the shared physical, chemical and biological properties of IgG, IgA, IgM, IgD and IgE in tabular form at pp. 227-29.

However, the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional.

Antibodies were known to be of five general types; each of the five types had been characterized as having substantial common structural, chemical and biological features.

The antigen-specific variable regions of antibodies vary.

It does not appear that persons of skill in the art consider knowledge of the amino acid sequence of the variable regions critical for purposes of assessing possession of an antibody.

Considering the facts, including the routine art-recognized method of making antigen-specific antibodies, the adequate description of antigen X, the well-defined structural characteristics for the classes, subclasses and isotypes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology was well developed and mature, one of skill in the art would have recognized that the disclosure of the adequately described antigen X put the applicant in possession of antibodies which bind to antigen X.

Technical Note

For an example discussion of the variable and hypervariable region sequence variation, see Kabat at pp. 286-300.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.